UNITED STATES DISTRICT COURT

DISTRICT OF SOUTH DAKOTA

WESTERN DIVISION

UNITED STATES OF AMERICA, Plaintiff, vs. 2035 INC., a corporation, and ROBERT L. LYTLE, an individual, d/b/a 2035 PMA and QLASERS PMA, Defendants.	CIV. 14-5075-JLV AMENDED ORDER OF PERMANENT INJUNCTION (Grammatical and Non-Substantive Revisions Only)

The Court held a hearing on Plaintiff's Motion for Preliminary Injunction on November 17, 2014, and entered a preliminary injunction on January 14, 2015 against 2035 Inc., a corporation, and Robert L. Lytle, an individual, who also goes by the name Dr. Larry Lytle and does business as 2035 PMA and QLasers PMA (collectively, "Defendants"). (Docket 48). On March 3 and 4, 2015, the court held a trial on the merits. Having considered all arguments raised at the preliminary injunction hearing, trial, and in the entire record in this case, the court finds that Defendants violated the Federal Food, Drug, and Cosmetic Act (the "FDCA"), 21 U.S.C. § 301 *et seq.*, and finds that Defendants, unless restrained by order of this court, will continue to violate the FDCA. The parties to this action stipulate that the court shall enter this order of permanent injunction. Pursuant to 21 U.S.C. § 332(a), Fed. R. Civ. P. 65 and the inherent equitable authority of the court, it is

ORDERED as follows:

1. This Court has jurisdiction over the subject matter of this action and has personal jurisdiction over all parties to this action pursuant to 28 U.S.C. §§ 1331 and 1345 and 21 U.S.C. § 332.

2. The Complaint states a cause of action against Defendants under the FDCA, 21 U.S.C. § 301 *et seq*.

3. Defendants violated the FDCA, 21 U.S.C. § 331(a), by introducing or delivering for introduction into interstate commerce and/or causing the introduction or delivery for introduction into interstate commerce of articles of device, as defined by 21 U.S.C. § 321(h), that were adulterated within the meaning of 21 U.S.C. § 351(f)(1)(B).

4. Defendants violated the FDCA, 21 U.S.C. § 331(a), by introducing or delivering for introduction into interstate commerce and/or causing the introduction or delivery for introduction into interstate commerce of articles of device, as defined by 21 U.S.C. § 321(h), that were misbranded within the meaning of 21 U.S.C. § 352(o).

5. Defendants violated the FDCA, 21 U.S.C. § 331(a), by introducing or delivering for introduction into interstate commerce and/or causing the introduction or delivery for introduction into interstate commerce of articles of device, as defined by 21 U.S.C. § 321(h), that were misbranded within the meaning of 21 U.S.C.§ 352(a).

6. Defendants violated the FDCA, 21 U.S.C. § 331(a), by introducing or delivering for introduction into interstate commerce and/or causing the introduction or delivery for introduction into interstate commerce of articles of device, as defined by 21 U.S.C. § 321(h), that were misbranded within the meaning of 21 U.S.C. § 352(j).

7. Defendants violated the FDCA, 21 U.S.C. § 331(k), by causing articles of device to become adulterated within the meaning of 21 U.S.C. § 351(f)(1)(B) and misbranded within the meaning of 21 U.S.C. §§ 352(o), (a), and (j), while such devices were held for sale after shipment of one or more of their components in interstate commerce.

8. Upon entry of this Order, Defendants and each and all of their directors, officers, agents, representatives, employees, attorneys, successors, and assigns, and any and all persons in active concert or participation with any of them (including franchisees, affiliates, private membership associations, and "doing business as" entities, and all persons or entities engaged in any part of the manufacture, design, processing, packing, labeling, holding, storing, and/or distribution of Defendants' devices, hereinafter collectively referred to as "Associated Persons"), who have received actual notice of the contents of this Order by personal service or otherwise, are hereby restrained and enjoined from directly or indirectly manufacturing, designing, processing, packing, labeling, holding, and/or distributing any article of device at or from 2035 1st Avenue, Rapid City, South Dakota, 3312 Jackson Boulevard, Rapid City, South Dakota,

and/or 3939 Canyon Lake Drive, Suite A, Rapid City, South Dakota, or at or from any other locations at which Defendants, now or in the future, directly or indirectly manufacture, design, process, pack, label, hold, and/or distribute devices unless and until:

A. Each of Defendants' devices are either: (1) the subject of an approved application for premarket approval under 21 U.S.C. § 360e(a); (2) the subject of an investigational device exemption under 21 U.S.C. § 360j(g); or (3) the subject of a cleared premarket notification under 21 U.S.C. § 360(k) for each of their intended uses;

B. Defendants select and retain at their expense an independent person or persons (the "Expert") to conduct comprehensive inspections of Defendants' operations and certify in writing to FDA: (1) that he or she has inspected Defendants' facilities and identified all devices manufactured and/or distributed by Defendants; (2) that each of Defendants' devices are either the subject of an approved application for premarket approval under 21 U.S.C. § 360e(a), the subject of an investigational device exemption under 21 U.S.C. § 360j(g), or the subject of a cleared premarket notification under 21 U.S.C. § 360(k); (3) that Defendants have corrected all violations set forth in FDA's Inspectional Observations ("Forms FDA-483") from all prior FDA

inspections since 2001 and the March 3, 2011 Warning Letter; and (4) whether, based upon the Expert's inspection, Defendants are operating in conformity with the FDCA, applicable regulations, and this Order. The Expert shall be qualified by education, training and experience to conduct such inspections, and shall be without personal or financial ties (other than a consulting agreement with Defendants) to Defendants' officers or employees or their immediate families. Defendants shall notify FDA in writing of the identity of the Expert within ten (10) business days of retaining such Expert;

C. Defendants report to FDA in writing the actions that they have taken to: (1) correct all violations brought to Defendants' attention by the Expert and/or set forth in FDA's Forms FDA 483 from all prior FDA inspections since 2001 and the March 3, 2011 Warning Letter; and (2) ensure that each of Defendants' devices is the subject of an approved application for premarket approval pursuant to 21 U.S.C. § 360e(a), the subject of an effective investigational device exemption pursuant to 21 U.S.C. § 360j(g), or the subject of a cleared premarket notification pursuant to 21 U.S.C. § 360(k);

D. Defendants recall and destroy, under FDA's supervision, all devices manufactured, processed, packed, labeled, held, and/or

distributed during the time period beginning June 30, 2001, through and including the date of entry of this Order. Defendants shall bear the costs of destruction and the costs of FDA's supervision. Defendants shall not dispose of any such products in a manner contrary to the provisions of the FDCA, any other federal law, or the laws of any state or Territory, as defined in the FDCA, in which the products are disposed;

E. Defendants permit inspection of their operations by FDA, and FDA, as it deems necessary to evaluate Defendants' compliance with the terms of this Order, inspects Defendants' operations to determine whether the requirements of this Order have been met, and whether Defendants are operating in conformity with the FDCA, applicable regulations, and this Order; and

F. FDA notifies Defendants in writing that Defendants appear to be in compliance with the requirements set forth in Paragraphs 8(A)-8(E) of this Order. Under no circumstances shall FDA's silence be construed as a substitute for written notification.

9. Defendants and each and all of their directors, officers, agents, representatives, employees, attorneys, successors, and assigns, and any and all of their Associated Persons who have received actual notice of this Order by personal service or otherwise, are enjoined under the provisions of 21 U.S.C. § 332(a) from directly or indirectly doing or causing to be done any act that:

A. Violates 21 U.S.C. § 331(a) by introducing or delivering for introduction into interstate commerce, or causing the introduction or delivery for introduction into interstate commerce of articles of device, as defined by 21 U.S.C. § 321(h), that are adulterated within the meaning of 21 U.S.C. § 351(f)(1)(B);

B. Violates 21 U.S.C. § 331(a) by introducing or delivering for introduction into interstate commerce, or causing the introduction or delivery for introduction into interstate commerce of articles of device, as defined by 21 U.S.C. § 321(h), that are misbranded within the meaning of 21 U.S.C. §§ 352(o), (a), and/or (j);

C. Violates 21 U.S.C. § 331(k) by causing devices to become adulterated within the meaning of 21 U.S.C. § 351(f)(1)(B), or misbranded within the meaning of 21 U.S.C. §§ 352(o), (a), and/or (j), while such devices are held for sale after shipment in interstate commerce; or

D. Fails to implement and continuously maintain the requirements of this Order.

10. After Defendants have complied with Paragraphs 8(A)-(E) and FDA has notified Defendants in writing pursuant to Paragraph 8(F), Defendants shall retain an independent person or persons (the "Auditor") at Defendants' expense

to conduct audit inspections of Defendants' operations not less than once every six (6) months for a period of five (5) years. The Auditor shall be qualified by education, training and experience to conduct such inspections, and shall be without personal or financial ties (other than a consulting agreement with Defendants) to Defendants' officers or employees or their immediate families. The Auditor may be the same person or persons described as the Expert in Paragraph 8(B).

A. At the conclusion of each audit inspection, the Auditor shall prepare a written audit report (the "Audit Report") analyzing whether Defendants are operating in compliance with the FDCA, applicable regulations, and this Order, and identifying in detail any deviations from the foregoing ("Audit Report Observations"). As part of every Audit Report, except the first, the Auditor shall assess the adequacy of corrective actions taken by Defendants to correct all previous Audit Report Observations. The Audit Reports shall be delivered contemporaneously to Defendants and FDA by courier service or overnight delivery service no later than ten (10) business days after the date the audit inspections are completed. If any Audit Reports identify any deviations from the FDCA, applicable regulations, and/or this Order, FDA may, in its discretion, require that the five (5) year auditing cycle be extended or begin anew. In addition, Defendants shall maintain

complete Audit Reports and all of their underlying data in separate files at their facilities and shall promptly make the Audit Reports and underlying data available to FDA upon request.

B. If an Audit Report contains any adverse Audit Report Observations, Defendants shall, within twenty (20) business days after receipt of the Audit Report, correct those observations unless FDA notifies Defendants that a shorter time period is necessary. If, after receiving the Audit Report, Defendants believe that correction of any adverse Audit Report Observation will take longer than twenty (20) business days, Defendants shall, within ten (10) business days after receipt of the Audit Report, propose a schedule for completing corrections ("Correction Schedule") and provide justification for the additional time. That Correction Schedule must be reviewed and approved by FDA in writing prior to implementation. Defendants shall complete all corrections according to the approved Correction Schedule. Within ten (10) business days after Defendants' receipt of an Audit Report, or within the time period provided in a Correction Schedule approved by FDA, the Auditor shall review the actions taken by Defendants to correct the adverse Audit Report Observation(s). Within two (2) business days after beginning that review, the Auditor shall report in

writing to FDA whether each of the adverse Audit Report Observations has been corrected and, if not, which adverse Audit Report Observations remain uncorrected.

11. If, at any time after this Order has been entered, FDA determines, based on the results of an inspection, an analysis of samples, a report or data prepared or submitted by Defendants, the Expert or the Auditor pursuant to this Order, or any other information, that Defendants or Associated Persons have failed to comply with any provision of this Order, or have violated the FDCA or applicable regulations, or that additional corrective actions are necessary to achieve compliance with this Order, the FDCA, or applicable regulations, FDA may, as and when it deems necessary, order Defendants in writing to take appropriate actions, and Defendants shall implement such order immediately upon receipt. Such actions may include, but are not limited to, the following:

A. Cease manufacturing, designing, processing, packing, labeling, holding, storing, and/or distributing devices;

B. Revise, modify, or expand any report(s) prepared pursuant to this Order;

C. Submit additional notifications, reports, or any other materials or information to FDA;

D. Recall, at Defendants' sole expense, adulterated or misbranded devices or components manufactured, distributed, and/or sold by Defendants and/or their Associated Persons, and/or that are

under the custody and control of Defendants' agents, distributors, customers, consumers or Associated Persons;

E. Issue a safety alert, public health advisory, and/or press release; and

F. Take any other corrective action(s) as FDA, in its discretion, deems necessary to protect the public health and/or to bring Defendants into compliance with FDCA, applicable regulations, and this Order.

12. Any cessation of operations described in Paragraph 11 shall continue until Defendants receive written notification from FDA that Defendants appear to be in compliance with the FDCA, applicable regulations, and this Order. The costs of FDA inspections, sampling, testing, travel time, and subsistence expenses to implement the remedies set forth in Paragraph 11 shall be borne by Defendants at the rates specified in Paragraph 14.

13. Representatives of the FDA shall be permitted, at reasonable times and without prior notice and as and when FDA deems necessary, to make inspections of Defendants' and Associated Persons' operations and, without prior notice, take any other measures necessary to monitor and to ensure continuing compliance with the terms of this Order. During such inspections, FDA representatives shall be permitted: access to buildings, equipment, in-process and finished materials, containers, and labeling therein; to take photographs and make video recordings; to take samples of Defendants'

materials and products, containers, and labeling; and to examine and copy all records relating to the receipt, manufacture, design, processing, packing, labeling, holding, and distribution of any and all devices. The inspections shall be permitted upon presenting a copy of this Order and appropriate credentials. The inspection authority granted by this Order is separate from, and in addition to, the authority to make inspections under the FDCA, 21 U.S.C. § 374. In addition, to ensure Defendants' compliance with this Order, Plaintiff and FDA are authorized to take any other measures necessary to monitor and to ensure Defendants' continuing compliance with this Order as and when they deem necessary by all lawful means, including but not limited to using representatives posing as a customer or potential customer to contact Defendants' websites, Associated Persons, and/or any other person or entity managed or controlled in whole or in part by Defendants without the necessity of identification or prior notice.

14. Defendants shall reimburse FDA for the costs of all FDA inspections, investigations, supervision, reviews, examinations, and analyses that FDA deems necessary to evaluate Defendants' compliance with this Order. The costs of such inspections shall be borne by Defendants at the prevailing rates in effect at the time the costs are incurred. As of the date of entry of this Order these rates are: $89.35 per hour or fraction thereof per representative for inspection work; $107.09 per hour or fraction thereof per representative for analytical or review work; $0.575 per mile for travel expenses by automobile;

government rate or the equivalent for travel by air or other means; and the published government per diem rate or the equivalent for the areas in which the inspections are performed per-day, per-representative for subsistence expenses, where necessary. In the event that the standard rates applicable to FDA supervision of Court-ordered compliance are modified, these rates shall be increased or decreased without further order of the Court.

15. Within five (5) business days after the entry of this Order, Defendants shall post a copy of this Order in the employee common areas at 2035 1st Avenue, Rapid City, South Dakota, 3312 Jackson Boulevard, Rapid City, South Dakota, 3939 Canyon Lake Drive, Suite A, Rapid City, South Dakota, and at any other locations at which Defendants manufacture, design, process, pack, label, hold, and/or distribute devices. The Order shall be posted in a location and manner to ensure that it will be viewed by Defendants' employees. Defendants shall ensure that the Order remains posted in its employee common areas for as long as the Order remains in effect.

16. Within five (5) business days after the entry of this Order, Defendants shall provide a copy of this Order, by personal service or certified mail (restricted delivery, return receipt requested), to each and all of their directors, officers, agents, representatives, employees, attorneys, successors, and assigns, and any and all persons in active concert or participation with any of them, including any Associated Persons. Within twenty (20) business days after the entry of this Order, Defendants shall provide to FDA an affidavit

stating the fact and manner of compliance with this Paragraph, identifying the names, addresses, and positions of all persons or entities who have received a copy of this Order pursuant to this Paragraph and attaching copies of the executed certified mail return receipts.

17. In the event Defendants become associated, at any time after the entry of this Order, with new Associated Person(s), Defendants shall within ten (10) business days after the commencement of such association: (a) provide a copy of this Order to each such Associated Person(s) by personal service or certified mail (restricted delivery, return receipt requested); and (b) provide to FDA an affidavit stating the fact and manner of compliance with this Paragraph, identifying the names, addresses, and positions of all persons or entities who received a copy of this Order pursuant to this Paragraph, and attaching copies of the executed certified mail return receipts.

18. Defendants shall notify FDA in writing at least fifteen (15) business days before any change in ownership, character, or name of its business, such as dissolution, assignment, or sale resulting in the emergence of a successor entity, the creation or dissolution of subsidiaries, franchisees, affiliates, or "doing business as" entities, or any other change in the structure of Defendant 2035, Inc., and/or the entities 2035 PMA and QLasers PMA, or in the sale or assignment of any business assets such as buildings, equipment, or inventory, that may affect compliance with this Order. Defendants shall provide a copy of this Order to any potential successor or assignee at least fifteen (15) business

days before any sale or assignment. Defendants shall furnish FDA with an affidavit of compliance with this Paragraph no later than ten (10) business days prior to such assignment, restructuring or change in ownership.

19. In accordance with the procedures described in subparagraphs A - C of this Paragraph, Defendants shall make restitution to all purchasers of Defendants' devices since June 30, 2001, whether such purchaser obtained the devices directly from Defendants or through one of Defendants' distributors, resellers or Associated Persons. Restitution shall include the full amount paid by the purchaser, including any shipping and handling costs.

A. Within thirty (30) business days of the entry of this Order, Defendants shall promptly provide to Plaintiff, and a Court-appointed Special Master whose services shall be paid by the Defendants if appointed, all records necessary to determine: (1) the identities, addresses and phone numbers of the individuals and entities who purchased Defendants' devices from June 30, 2001, to the date of this Order; (2) the dates and quantities of Defendants' devices ordered and the price paid for such products including any costs of shipping paid by the purchasers (less any refunds already paid by Defendants to such purchasers); (3) Defendants' manufacturing costs for such products; and (4) the profits realized by Defendants from the sale of such products. These records shall include but not be

limited to state and federal tax returns; bank records; shipping records; sales invoices; accounting records, including certified financial statements; a truthful and fully-executed copy of Department of Justice Form OBD-500; and any other records as the Court or the Special Master may request. Within thirty-five (35) business days after the entry of this Order, Defendants shall provide to FDA an affidavit stating the fact and manner of compliance with this Paragraph. In the event such records cannot be provided by Defendants, an affidavit explaining the inability to produce some or all of the records shall be filed with the court within thirty-five (35) business days of the entry of this Order.

B. Upon entry of this Order, Defendants and Associated Persons shall immediately refrain from disposing of or transferring any assets that may interfere with implementation of restitution payments. In addition, Defendants and Associated Persons are prohibited from destroying, discarding, altering, transferring or otherwise making unavailable any documents and records in electronic format or otherwise within the custody or control of the Defendants and Associated Persons.

C. Within forty-five (45) business days of entry of this Order, Defendants shall submit to this Court and Plaintiff a proposed

restitution plan, which may include the name of an independent contractor to effectuate restitution payments at Defendants' expense, along with the proposed terms of engagement between Defendants and the independent contractor.

20. All notifications, correspondence and communications required to be sent to FDA by the terms of this Order shall be prominently marked "Order Correspondence" and shall be addressed to the District Director, Minneapolis District Office, United States Food and Drug Administration, 250 Marquette Avenue, Suite 600, Minneapolis, Minnesota 55401, and shall reference this civil action by case name and civil action number.

21. If any Defendant fails to comply with any of the provisions of this Order including any time frame imposed by this Order, then on written notice of the United States in this proceeding, Defendants shall pay to the United States of America the sum of ten thousand dollars ($10,000) in liquidated damages for each violation of this Order and an additional ten thousand dollars ($10,000) in liquidated damages for each day such violation continues.

22. Should the United States bring and prevail in a contempt action to enforce the terms of this Order, Defendants shall, in addition to other remedies, reimburse the United States for its attorneys' fees, investigation expenses, expert witness fees, travel expenses incurred by attorneys and witnesses, and administrative court costs relating to such contempt proceedings.

23. All decisions specified in this Order shall be vested in the discretion of FDA and shall be final. If contested by Defendants, FDA's decisions under this Order shall be reviewed by the Court under the arbitrary and capricious standard set forth in 5 U.S.C. § 706(2)(A). Review shall be based exclusively on the written record before FDA at the time the decision was made. No discovery shall be taken by either party.

24. This Court retains jurisdiction of this action for the purpose of enforcing or modifying this Order and for the purpose of granting such additional relief as may be necessary or appropriate.

Dated October 13, 2015.

BY THE COURT:

/s/ *Jeffrey L. Viken*
JEFFREY L. VIKEN
CHIEF JUDGE